

REMARKS

Claims 12, 14, 15, 17, 21, 22, 26, 30 and 31 are pending and claim 12 is independent. New claims 30 and 31 are added, which are supported by at least the specification at page 9, line 15 to page 10, line 20. Thus, no new matter has been added.

In view of the following remarks, reconsideration of this application is respectfully requested.

Issue under 35 U.S.C. §102(b)

Claims 12, 14, 15, 17, 21, 22 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bijlsma et al. (WO 00/57727). This rejection is respectfully traversed.

The Present Invention and its Advantages

The present invention is directed to a method for ameliorating or treating an inflammatory bowel disease (IBD), comprising administering a composition comprising galactomannan as an agent for lowering the activity of myeloperoxidase and TNF- α to a patient suffering from said IBD, wherein said galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5 (w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with β -mannanase (claim 12) (emphasis added).

Further, the present invention achieves unexpectedly superior effects with respect to the administered ingredient and diseases. In particular, the test data in Test Examples 1-1 to 1-3 and Figs. 1-3 demonstrates superior results with respect to the present invention. Specifically, the test data demonstrates that the presently employed galactomannan not only shows histologically ameliorative actions for inflammatory bowel diseases, but also has suppressive action on inflammation, and lowers the activity of myeloperoxidase (MPO) and TNF- α .

Also, the test data in Test Examples 2-1 to 2-4 demonstrates superior results with respect to the present invention. For instance, a review of the results of Tables 6, 8, 10 and 12 reveals that the liquid foods of Examples 2-1 to 2-4 exhibit excellent effects for patients with ulcerative

colitis, Crohn's disease, and bowel Behçet disease. In contrast, the liquid foods of Comparative Examples 2-1, 2-3, 2-4, 2-6 and 2-8 are found to show only slight efficacy for patients with ulcerative colitis, Crohn's disease, and bowel Behçet disease, and the liquid foods of Comparative Examples 2-2, 2-5, 2-7, and 2-9 are not found to show any efficacy for any one of the patients.

Distinctions over the Cited Art

As recited in the claims, the present composition requires at least a specific degraded galactomannan which has an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with β -mannanase.

Bijlsma

Bijlsma relates to a nutritional composition comprising non-digestible polysaccharides which contain a negatively charged groups such as carboxyl, sulphate or phosphate for the prevention or treatment of inflammatory bowel disease (IBD) (see Abstract, page 3, lines 16-20 and page 6, lines 4-6 of Bijlsma).

However, the presently claimed degraded galactomannan is distinguishable from Bijlsma's galactomannan. Particularly, the galactomannan of Bijlsma requires one or more acid groups (carboxyl, sulphate or phosphate), whereas no modification by acid groups is made to galactomannan of the present invention. The galactomannan of independent claim 12 does not allow such acid groups since the claimed galactomannan is produced by hydrolyzing guar gum with β -mannanase. It is clear that β -mannanase as an enzyme is used for the hydrolysis, thereby, making no modification with acid groups. In at least this respect, the present invention is distinct over Bijlsma.

Also, the Examiner refers to Example 1 of Bijlsma at page 2 of the Office Action. Such Example 1, however, relates to an embodiment where pyridine sulfur trioxide is added to slightly hydrolyzed guar gum so as to introduce sulphate therein and resultantly to produce the negatively charged polysaccharide such as galactomann. This is quite different from the present invention. In the present invention, guar gum is hydrolyzed with β -mannanase to produce a galactomannan

without the necessity of such negatively charged sulphate group. Clearly, Bijlsman fails to disclose or suggest hydrolysis of guar gum with β -mannanase. Also, Example 6 of Bijlsma refers to the embodiment mixing carboxydextran into food, however, such carboxydextran is a material different from the claimed invention.

Thus, the teachings of Bijlsma are distinct from those of the present invention and therefore, Bijlsma fails to teach or suggest the present invention. Reconsideration and withdrawal of the anticipation rejection are respectfully requested.

Issue under 35 U.S.C. §103(a)

Claims 12, 14, 15, 17, 21, 22 and 26 stand rejected under 35 U.S.C. §103(a) as being obvious over Bijlsma in combination with De La Torre et al. (Riviste Italiana Di Nutrizione Parenterale Ed Enterale, Vol. 21, No. 3, pp 105-111, Wichig Editore, Milano, IT, January 1, 2003). This rejection is respectfully requested.

The deficiencies of Bijlsma cannot be cured by De La Torre, which discloses a degraded galactomannan (i.e., partially hydrolyzed guar gum (PHGG), which results in a short chain fatty acid (SCFA)) for the treatment of IBD. Specifically, the galactomannan of De La Torres has a molecular weight of 220,000 daltons (see page right column at page 108), which is outside of the claimed range of 8,000-50,000. Also, De La Torres fails to disclose or suggest hydrolysis of guar gum with a specific β -mannanase. Thus, even if these cited references were to be combined, the present invention cannot be achieved. Reconsideration and withdrawal of the obviousness rejection are accordingly requested.

New Claims 30 and 31

Claims 30 and 31, depending on claim 12, have been added, and are inherently or expressly supported by page 9, line 15-page 10, line 20 of the specification. At this point, the present specification clearly discloses that *"By the procedures described above, degraded galactomannan is obtained. The resulting degraded product can be used as it is, or can be used after being washed with water or the like if desired."* Thus, after the hydrolysis procedure, the

degraded galactomannan does not require any chemical treatment since the galactomannan can be used as it is or washed by water (see page 10, lines 15-20 of the specification). Therefore, the process for producing galactomannan consists essentially of hydrolyzing guar gum with β -mannanase (e.g., without any further chemical processing). Accordingly, it is evident that claims 30 and 31 are inherently or expressly supported by such disclosure.

Also, the claimed features recited in new claims 30 and 31 are also absent from the cited references of record. For instance, Biljsman requires necessarily a chemical treatment of hydrolyzed guar gum by e.g., pyridine sulfur trioxide in order to introduce the negatively charged groups therein. However, the present invention does not require such chemical processing or treatment. Accordingly, the present invention is believed to be allowable for the same reasons as claim 12.


In view of the above remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Registration No. 42874 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

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